

for recovery then it is part of a pharmaceutical process and is not a waste management unit.

Wastewater means any portion of an individual wastewater stream or any aggregation of wastewater streams.

Wastewater stream means water that is discarded from a PMPU through a single POD, that contains an annual average concentration of partially soluble and/or soluble HAP compounds of at least 5 parts per million by weight and a load of at least 0.05 kg/yr, and that is not exempted by the provisions of § 63.1256(a)(3). For the purposes of this subpart, noncontact cooling water is not considered a wastewater stream. Wastewater streams are generated by both process operations and maintenance activities.

Wastewater tank means a stationary waste management unit that is designed to contain an accumulation of wastewater or residuals and is constructed primarily of nonearthen materials (e.g., wood, concrete, steel, plastic) which provide structural support. Wastewater tanks used for flow equalization are included in this definition.

Water seal controls means a seal pot, p-leg trap, or other type of trap filled with water (e.g., flooded sewers that maintain water levels adequate to prevent air flow through the system) that creates a water barrier between the sewer line and the atmosphere. The water level of the seal must be maintained in the vertical leg of a drain in order to be considered a water seal.

§ 63.1252 Standards: General.

Each owner or operator of any affected source subject to the provisions of this subpart shall control HAP emissions to the level specified in this section on and after the compliance dates specified in § 63.1250(f). Compliance with the emission limits may be demonstrated initially through the provisions of § 63.1257 (Test methods and compliance procedures) and continuously through the provisions of § 63.1258 (Monitoring requirements).

(a) *Opening of a safety device.* Opening of a safety device, as defined in § 63.1251, is allowed at any time conditions require it to do so to avoid unsafe conditions.

(b) *Closed-vent systems.* The owner or operator of a closed-vent system that contains bypass lines that could divert a vent stream away from a control device used to comply with the requirements in §§ 63.1253, 63.1254, and 63.1256 shall comply with the requirements of Table 4 to this subpart and paragraph (b)(1) or (2) of this section. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, rupture disks and pressure relief valves needed for safety purposes are not subject to this paragraph.

(1) Install, calibrate, maintain, and operate a flow indicator that determines whether vent stream flow is present at least once every 15 minutes. Records shall be maintained as specified in § 63.1259(i)(6)(i). The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere; or

(2) Secure the bypass line valve in the closed position with a car seal or lock and key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line. Records shall be maintained as specified in § 63.1259(i)(6)(ii).

(c) *Heat exchange systems.* Except as provided in paragraph (c)(2) of this section, owners and operators of affected sources shall comply with the requirements in paragraph (c)(1) of this section for heat exchange systems that cool process equipment or materials used in pharmaceutical manufacturing operations.

(1) The heat exchange system shall be treated according to the provisions of § 63.104, except that the monitoring frequency shall be no less than quarterly.

(2) For identifying leaking equipment, the owner or operator of heat exchange systems on equipment which meet current good manufacturing practice (CGMP) requirements of 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system leaks around the reactor.

(d) *Emissions averaging provisions.* Except as specified in paragraphs (d)(1)

through (5) of this section, owners or operators of storage tanks or processes subject to the provisions of §§ 63.1253 and 63.1254 may choose to comply by using emissions averaging requirements specified in § 63.1257(g) or (h) for any storage tank or process.

(1) A State may prohibit averaging of HAP emissions and require the owner or operator of an existing source to comply with the provisions in §§ 63.1253 and 63.1254.

(2) Only emission sources subject to the requirements of § 63.1253(b)(1) and (c)(1) or § 63.1254(a)(2), (a)(3)(ii)(A) or (a)(3)(iii) may be included in any averaging group.

(3) Processes which have been permanently shutdown or storage tanks permanently taken out of HAP service may not be included in any averaging group.

(4) Processes and storage tanks already controlled on or before November 15, 1990 may not be included in an emissions averaging group, except where the level of control is increased after November 15, 1990. In these cases, the uncontrolled emissions shall be the controlled emissions as calculated on November 15, 1990 for the purpose of determining the uncontrolled emissions as specified in § 63.1257(g) and (h).

(5) Emission points controlled to comply with a State or Federal rule other than this subpart may not be included in an emission averaging group, unless the level of control has been increased after November 15, 1990 above what is required by the other State or Federal rule. Only the control above what is required by the other State or Federal rule will be credited. However, if an emission point has been used to generate emissions averaging credit in an approved emissions average, and the point is subsequently made subject to a State or Federal rule other than this subpart, the point can continue to generate emissions averaging credit for the purpose of complying with the previously approved average.

(6) Not more than 20 processes subject to § 63.1254(a)(2)(i), 20 storage tanks subject to § 63.1253(b)(1), and 20 storage tanks subject to § 63.1253(c)(1)(i) at an affected source may be included in an emissions averaging group.

(7) Compliance with the emissions standards in § 63.1253 shall be satisfied when the annual percent reduction efficiency is greater than or equal to 90 percent for those tanks meeting the requirements of § 63.1253(a)(1) and 95 percent for those tanks meeting the requirements of § 63.1253(a)(2), as demonstrated using the test methods and compliance procedures specified in § 63.1257(g).

(8) Compliance with the emissions standards in § 63.1254(a)(2) shall be satisfied when the annual percent reduction efficiency is greater than or equal to 93 percent, as demonstrated using the test methods and compliance procedures specified in § 63.1257(h).

(e) *Pollution prevention alternative.* Except as provided in paragraph (e)(1) of this section, owners and operators may choose to meet the pollution prevention alternative requirement specified in either paragraph (e)(2) or (3) of this section for any PMPU, in lieu of the requirements specified in §§ 63.1253, 63.1254, 63.1255, and 63.1256. Compliance with paragraphs (e)(2) and (3) of this section shall be demonstrated through the procedures in § 63.1257(f).

(1) The HAP that are generated in the PMPU that are not part of the production-indexed consumption factor must be controlled according to the requirements of §§ 63.1253, 63.1254, 63.1255, and 63.1256. The HAP that are generated as a result of combustion control of emissions must be controlled according to the requirements of paragraph (g) of this section.

(2) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 75 percent from a 3 year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is the lesser time period. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved

by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(3) Both requirements specified in paragraphs (e)(3)(i) and (ii) of this section are met.

(i) The production-indexed HAP consumption factor (kg HAP consumed/kg produced) shall be reduced by at least 50 percent from a 3-year average baseline established no earlier than the 1987 calendar year, or for the time period from startup of the process until the present in which the PMPU was operational and data are available, whichever is less. If a time period less than 3 years is used to set the baseline, the data must represent at least 1 year's worth of data. For any reduction in the HAP factor achieved by reducing a HAP that is also a VOC, an equivalent reduction in the VOC factor is also required. For any reduction in the HAP factor that is achieved by reducing a HAP that is not a VOC, the VOC factor may not be increased.

(ii) The total PMPU HAP emissions shall be reduced by an amount, in kg/yr, that, when divided by the annual production rate, in kg/yr, and added to the reduction of the production-indexed HAP consumption factor, in kg/kg, yields a value of at least 75 percent of the average baseline HAP production-indexed consumption factor established according to paragraph (e)(3)(i) of this section according to the equation provided in § 63.1257(f)(2)(ii)(A). The total PMPU VOC emissions shall be reduced by an amount calculated according to the equation provided in § 63.1257(f)(2)(ii)(B). The annual reduction in HAP and VOC air emissions must be due to the use of the following control devices:

(A) Combustion control devices such as incinerators, flares or process heaters.

(B) Control devices such as condensers and carbon adsorbers whose recovered product is destroyed or shipped offsite for destruction.

(C) Any control device that does not ultimately allow for recycling of material back to the PMPU.

(D) Any control device for which the owner or operator can demonstrate that the use of the device in controlling HAP emissions will have no effect

on the production-indexed consumption factor for the PMPU.

(f) *Control requirements for certain liquid streams in open systems within a PMPU.* (1) The owner or operator shall comply with the provisions of Table 5 of this subpart, for each item of equipment meeting all the criteria specified in paragraphs (f)(2) through (4) and either paragraph (f)(5)(i) or (ii) of this section.

(2) The item of equipment is of a type identified in Table 5 of this subpart;

(3) The item of equipment is part of a PMPU, as defined in § 63.1251;

(4) The item of equipment is controlled less stringently than in Table 5 of this subpart and the item of equipment is not otherwise exempt from controls by the provisions of this subpart or subpart A of this part; and

(5) The item of equipment:

(i) Is a drain, drain hub, manhole, lift station, trench, pipe, or oil/water separator that conveys water with an annual average concentration greater than or equal to 1,300 parts per million by weight (ppmw) of partially soluble HAP compounds; or an annual average concentration greater than or equal to 5,200 ppmw of partially soluble and/or soluble HAP compounds. The annual average concentration shall be determined according to the procedures in § 63.1257(e)(1)(ii).

(ii) Is a tank that receives one or more streams that contain water with an annual average concentration greater than or equal to 1,300 ppmw of partially soluble HAP compounds, or greater than or equal to 5,200 ppmw of total partially soluble and/or soluble HAP compounds. The owner or operator of the source shall determine the average concentration of the stream at the inlet to the tank and according to the procedures in § 63.1257(e)(1)(ii).

(g) *Control requirements for halogenated vent streams that are controlled by combustion devices.* If a combustion device is used to comply with the provisions of §§ 63.1253 (storage tanks), 63.1254 (process vents), 63.1256(h) (wastewater vent streams) for a halogenated vent stream, then the vent stream shall be ducted to a halogen reduction device such as, but not limited to, a scrubber, before it is discharged

to the atmosphere. The halogen reduction device must reduce emissions by the amounts specified in either paragraph (g)(1) or (2) of this section.

(1) A halogen reduction device after the combustion control device must reduce overall emissions of hydrogen halides and halogens, as defined in § 63.1251, by 95 percent or to a concentration less than or equal to 20 ppmv.

(2) A halogen reduction device located before the combustion control device must reduce the halogen atom content of the vent stream to a concentration less than or equal to 20 ppmv.

§ 63.1253 Standards: Storage tanks.

(a) Except as provided in paragraphs (d) and (e) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(1) of this section is subject to the requirements of paragraph (b) of this section. Except as provided in paragraphs (d) and (e) of this section, the owner or operator of a storage tank meeting the criteria of paragraph (a)(2) of this section is subject to the requirements of paragraph (c) of this section. Compliance with the provisions of paragraphs (b) and (c) of this section is demonstrated using the initial compliance procedures in § 63.1257(c) and the monitoring requirements in § 63.1258.

(1) A storage tank with a design capacity greater than or equal to 38 m³ (10,000 gallons [gal]) but less than 75 m³ (20,000 gal), and storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

(2) A storage tank with a design capacity greater than or equal to 75 m³ (20,000 gal) storing a liquid for which the maximum true vapor pressure of total HAP is greater than or equal to 13.1 kPa (1.9 psia).

(b) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP by 90 percent by weight or greater;

(2) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760° C;

(3) Is a flare that meets the requirements of § 63.11(b); or

(4) Is a control device specified in § 63.1257(a)(4).

(c) The owner or operator of a storage tank shall equip the affected storage tank with either a fixed roof with internal floating roof, an external floating roof, an external floating roof converted to an internal floating roof, or a closed-vent system meeting the conditions of § 63.1252(b) with a control device that meets any of the following conditions:

(1) Reduces inlet emissions of total HAP as specified in paragraph (c)(1) (i) or (ii) of this section:

(i) By 95 percent by weight or greater; or (ii) If the owner or operator can demonstrate that a control device installed on a storage tank on or before April 2, 1997 is designed to reduce inlet emissions of total HAP by greater than or equal to 90 percent by weight but less than 95 percent by weight, then the control device is required to be operated to reduce inlet emissions of total HAP by 90 percent or greater.

(2) Is an enclosed combustion device that provides a minimum residence time of 0.5 seconds at a minimum temperature of 760° C;

(3) Is a flare that meets the requirements of § 63.11(b); or

(4) Is a control device specified in § 63.1257(a)(4).

(d) As an alternative standard, the owner or operator of an existing or new affected source may comply with the storage tank standards by routing storage tank vents to a control device achieving an outlet TOC concentration, as calibrated on methane or the predominant HAP, of 20 ppmv or less, and an outlet concentration of hydrogen halides and halogens of 20 ppmv or less. Compliance with the outlet concentrations shall be determined by the initial compliance procedures of § 63.1257(c)(4) and the continuous emission monitoring requirements of § 63.1258(b)(5).